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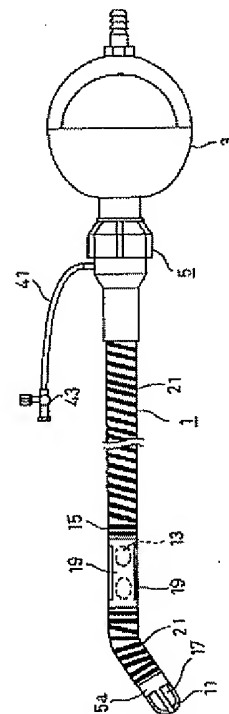
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(54) 【発明の名称】 カニユーレ及び補助循環装置

(57) 【要約】

【課題】 従来よりも外径寸法の細径化を図ることができ、しかも、柔軟性が高く折れ曲がりにくいカニユーレ及び補助循環装置を提供すること。

【解決手段】 補助循環装置は、カニユーレ1と血液ポンプ3とを備え、カニユーレ1は、吸入口11及び吐出口13を有する可撓性のチューブ15と、吸入口11からチューブ15内への流体の流入を許容する一方、チューブ15内から吸入口11外への流体の流出を阻止する吸入弁17と、チューブ15内から吐出口13外への流体の流出を許容する一方、吐出口13からチューブ15内への流体の流入を阻止する柔軟膜状の吐出弁19とを備えている。チューブ15の肉中には、補強部材21が固着されている。補強部材21は、帯状のステンレス線を螺旋状に巻回したもので、帯の一方の面を外周に向けると共に、その裏側となる他方の面を内周に向ける形で螺旋を描いている。



## 【特許請求の範囲】

【請求項 1】 一方の端に開口する吸入口、および該吸入口から設定距離を保って側壁に穿設された吐出口を有する可撓性の樹脂チューブと、前記吸入口に対して前記樹脂チューブの内側に設置され、前記吸入口から前記樹脂チューブ内への流体の流入を許容する一方、前記樹脂チューブ内から前記吸入口への流体の流出を阻止する柔軟膜状の吸入弁と、前記樹脂チューブの外周側で前記吐出口を覆って設置され、前記樹脂チューブ内から前記吐出口への流体の流出を許容する一方、前記吐出口から前記樹脂チューブ内への流体の流入を阻止する柔軟膜状の吐出弁とを備えたカニユーレにおいて、前記樹脂チューブと略同径の螺旋状に成形された金属からなり、前記樹脂チューブを巻回する形で該樹脂チューブに固着された補強部材を備えたことを特徴とするカニユーレ。

【請求項 2】 請求項 1 記載のカニユーレにおいて、前記補強部材が、長尺な帯状体からなり、該帯状体の一方の面が内周、他方の面が外周となる形で螺旋状に成形されていることを特徴とするカニユーレ。

【請求項 3】 請求項 1 又は請求項 2 のいずれかに記載のカニユーレと、該カニユーレの前記樹脂チューブの他方の端に連通する流出入口、および該流出入口に連通する液室を備え、該液室の容積を変化させることにより、前記流出入口を介して前記カニユーレから流体を吸入、または前記流出入口を介して前記カニユーレへ流体を吐出するポンプとを備えたことを特徴とする補助循環装置。

## 【発明の詳細な説明】

## 【0001】

【発明の属する技術分野】 本発明は、左心室ないし大動脈にかけて挿入されて、血液を左心室側から吸入して大動脈側に吐出することによる血流の補助循環に使用されるカニユーレと、このカニユーレを装着した補助循環装置に関する。

## 【0002】

【従来の技術】 周知のように、弁膜症等の慢性心不全や急性心筋梗塞、開心術後の心原性ショック等の進行性かつ不可逆性の心不全に対して、薬剤投与や酸素吸入等の治療の他に、機械的補助循環による処置が行われることがある。

【0003】 この機械的補助循環を実施する装置の一種として、本願出願人は、特開平 7-231934 号公報において、左心室ないし大動脈にかけて挿入されて、血液を左心室側から吸入して大動脈側に吐出するカニユーレと、このカニユーレを装着した補助循環装置とを既に提案している。このカニユーレ及び補助循環装置によれば、心臓の負担を増加させることなく、流量補助と拍動的な圧補助とが実現でき、心停止時の補助循環としてもきわめて有効であった。

## 【0004】

【発明が解決しようとする課題】 しかしながら、上記従来のカニユーレ及び補助循環装置によれば、まず、必要な血液流量を確保するだけの内径が必要で、その上で、カニユーレに内部の増圧および減圧に耐えるだけの強度が必要となるため、これらの条件を満足させるには、樹脂製チューブの外径をかなり太く形成せざるを得ず、カニユーレを血管内に挿入する際に患者の負担が大ききという問題があった。

10 【0005】 また、この様に外径が太くて相応に強度のある樹脂チューブは、柔軟性に欠けるものとなりやすいため、湾曲した血管に挿入した場合に折れ曲がり（キンク）が発生しやすく、万一折れ曲がった場合には、挿入時であれば挿入操作が困難になり、補助循環実施中であれば早急に対処をしないと所期の補助循環がなされなくなるという問題もあった。

20 【0006】 本発明は、上記問題を解決するためになされたものであり、その目的は、従来よりも外径寸法の細径化を図ることができ、しかも、柔軟性が高く折れ曲がりにくいカニユーレと、そのカニユーレを装着した補助循環装置を提供することにある。

## 【0007】

【課題を解決するための手段、および発明の効果】 上述の目的を達成するため、本発明は、請求項 1 記載の通り、一方の端に開口する吸入口、および該吸入口から設定距離を保って側壁に穿設された吐出口を有する可撓性の樹脂チューブと、前記吸入口に対して前記樹脂チューブの内側に設置され、前記吸入口から前記樹脂チューブ内への流体の流入を許容する一方、前記樹脂チューブ内から前記吸入口への流体の流出を阻止する柔軟膜状の吸入弁と、前記樹脂チューブの外周側で前記吐出口を覆って設置され、前記樹脂チューブ内から前記吐出口への流体の流出を許容する一方、前記吐出口から前記樹脂チューブ内への流体の流入を阻止する柔軟膜状の吐出弁とを備えたカニユーレにおいて、前記樹脂チューブと略同径の螺旋状に成形された金属からなり、前記樹脂チューブを巻回する形で該樹脂チューブに固着された補強部材を備えたことを特徴とする。

30 【0008】 上記構成において、樹脂チューブと略同径とは、少なくとも、樹脂チューブの内径以上の外径を有し、かつ樹脂チューブの外径以下の内径を有することを意味し、このようなサイズとすることにより、補強部材によって樹脂チューブを巻回する形で、補強部材を、樹脂チューブの外周、内周、又は肉中のいずれかに固着することができる。

50 【0009】 以上のように構成された本発明のカニユーレは、補強部材を備えた樹脂チューブ（以下、単にチューブともいう）を、例えば右鎖骨下動脈から吸入口側を先頭にして挿入し、大動脈弁を挟んで吸入口を左心室側に吐出口を大動脈側に位置させて使用される。この時、

チューブの他端（手元側端）は体外に残しておき、その後単一の流出入口から吸入・吐出を交互に行うポンプの流出入口に接続する。また、使用に先だってカニューレおよびポンプ内の空気抜きを実施する。

【0010】ポンプが吸入行程にあるときには、チューブ内が相対的に陰圧状態となるので、吸入弁が開弁状態となり、左心室内の血液が吸入口からチューブ内へ流入する。他方、ポンプが吐出行程にあるときには、チューブ内が相対的に陽圧状態となるので、吐出弁が開弁状態となり、チューブ内の血液が大動脈へと流出する。また、この際、ポンプの吐出圧はチューブ内の血液を介して大動脈側の血液に伝達され、大動脈内の血圧を増圧する。

【0011】このように、ポンプの吸入・吐出に応じて左心室から大動脈への血流を発生させ、流量補助ができる。しかも、ポンプの吸入・吐出行程に対応してチューブ内の圧力が陰圧から陽圧、陽圧から陰圧へと交互に切り替わるので、拍動的な圧補助ができる。血液ポンプを、例えば左心室収縮時に吸入し左心室拡張時に吐出するように、心臓の拍動に合わせて移動させれば、左心室収縮時には左心室内の血液を吸入するので収縮に際しての心臓の負担が低減され、左心室拡張時には大動脈に供給される血液が増大されると同時に大動脈内の血圧が増圧される。なお、左心室拡張時には左心室と大動脈とが大動脈弁で遮断されるので、カニューレから大動脈内に吐出された血液が左心室側へ流入することはない。

【0012】したがって、心臓の負担を増加させることなく、流量補助と拍動的な圧補助とが実現される。また、心停止状態にあっても上述のように血流と拍動とを確保できるので、心停止時の補助循環としてきわめて有効である。また特に、本発明のカニューレは、樹脂チューブに上述の如き補強部材を設けてあるので、チューブの肉厚を薄くしても内部の増圧および減圧に耐えるだけの強度がある。そのため、従来品と同等の内径を設定した場合でも、従来の樹脂チューブより外径を細くすることができ、血行障害等を招きにくく、血管内への挿入時における患者の負担が軽減される。また、補強部材は、螺旋状に巻回される形で固着されているので、樹脂チューブが本来有する柔軟性を失うことはなく、むしろ、チューブの強度が向上した分だけ、樹脂自体の肉厚を薄くでき、しかも、従来以上に柔らかい樹脂材料を使うこともできるので、従来よりも柔軟性は高くすることができ、湾曲した血管に挿入した場合にも折れ曲がりが発生しない。

【0013】ところで、上記補強部材は、金属線材を螺旋状に成形したものであれば、例えば、金属線材自体の断面形状等については特に限定されないが、請求項2記載の如く、前記補強部材が、長尺な帯状体からなり、該帯状体の一方の面が内周、他方の面が外周となる形で螺旋状に成形されていると、必要な強度を確保しながら、

より細径化を図ることができる点で有利である。

【0014】すなわち、ここでいう帯状体は、ある程度の幅と、その幅に比べるとかなり薄い厚さを有するものであるが、この様な帯状体を、帯状体の一方の面が内周、他方の面が外周となる形で螺旋状に成形すれば、帯状体の厚さ寸法が多少薄くなっても、幅寸法を大きくすることで必要な強度を確保できるので、同程度の強度となるように丸棒状、角棒状の線材を螺旋状に成形した場合に比べ、補強部材自体の肉厚を薄くできる。したがって、カニューレの細径化を図るにはきわめて好適である。

【0015】更に、請求項3記載の補助循環装置は、請求項1又は請求項2に記載のカニューレと、該カニューレの前記樹脂チューブの他方の端に連通する流出入口、および該流出入口に連通する液室を備え、該液室の容積を変化させることにより、前記流出入口を介して前記カニューレから流体を吸入、または前記流出入口を介して前記カニューレへ流体を吐出するポンプとを備えたので、上記カニューレを使った補助循環を実施でき、上記カニューレについて述べたとおりの効果を発揮する。

【0016】

【発明の実施の形態】次に、本発明の実施形態を図面に基いて説明する。なお、以下に説明するカニューレ及び補助循環装置は、本発明の実施形態の一例に過ぎず、本発明の構成手段は下記の具体的な装置等に限定されない。

【0017】補助循環装置は、図1に示す様に、カニューレ1と血液ポンプ3とを備え、両者がコネクタ5によって接続されている。上記カニューレ1は、吸入口11及び吐出口13を有する可撓性のチューブ15と、吸入口11に対してチューブ15の内側に設置され、吸入口11からチューブ15内への流体の流入を許容する一方、チューブ15内から吸入口11外への流体の流出を阻止する柔軟膜状の吸入弁17と、チューブ15の外周側で吐出口13を覆って設置され、チューブ15内から吐出口13外への流体の流出を許容する一方、吐出口13からチューブ15内への流体の流入を阻止する柔軟膜状の吐出弁19とを備えている。

【0018】この内、吸入口11は、チューブ15の最先端に装着された先端部材15aに4つ穿設され、その内側にセグメント化ポリウレタン製の吸入弁17が装着されている。この吸入弁17は、図2(b)の模式図に示す様に、吸入口11の内周側に密着する形状で、その中心だけが先端部材15aの内側に接着されている。そのため、チューブ15の内部が陰圧になった場合は、図2(a)に示す様に、外部から流入する流体に逆らわない形状に変形する一方、チューブ15の内部が陽圧になった場合は、図2(b)に示す様に、吸入口11の内周側に密着する形状に復帰し、外部への流体の流出を阻止する。

【0019】一方、吐出口13は、2個1組として120度回転対称な位置に3箇所（即ち、計6個）形成され、その外周を覆うように、セグメント化ポリウレタン製の吐出弁19が装着されている。吐出弁19は、チューブ15の外周に密着する筒状で、両端部がチューブ15の外周面に接着されている。また、この吐出弁19には、吐出口13とは互い違いとなる120度回転対称な位置に、計3本のスリット19aが形成されている。これにより、チューブ15の内部が陰圧になった場合は、吐出弁19が吐出口13を覆って密着する一方、チューブ15の内部が陽圧になった場合は、吐出弁19が図2

(b)に示す様に膨張し、吐出口13から流出して吐出口13と吐出弁19との間に流入した流体は、スリット19aを介して外部に流出する。

【0020】更に、上記カニューレ1における特徴的な構成として、チューブ15の肉中に、図1に示す通り、補強部材21が固着されている。この補強部材21は、帯状のステンレス線を螺旋状に巻回したもので、帯の一方の面を外周に向けると共に、その裏側となる他方の面を内周に向ける形で螺旋を描いている。また、補強部材21は、チューブ15の先端付近から吐出口13よりも遠位端側までと、吐出口13よりも近位端側からチューブ15の近位端付近までの2つの領域に固着され、その間の吐出口13付近には配設されていない。

【0021】この様な補強部材21を設けると、チューブ15の強度が向上するため、従来と同等の強度および内径寸法を確保しながら、チューブ15の外径寸法を細くすることができる。より具体的には、補強部材21を設けていない従来品の場合、5.5mmの内径を確保すると約7.5~8.5mm程度の外径になっていたものが、補強部材21を設けることで、同じ5.5mmの内径を確保しても外径を約6.5~7.5mm程度にまで細径化できるようになる。したがって、より血管径の細い患者への適用も可能になり、また、血行障害等を招くケースもより少なくなるものと期待される。

【0022】さて一方、血液ポンプ3は、図2(a)、同図(b)に示す様に、内部に変形自在な柔軟膜状の隔壁31によって仕切られた液室33と気室35とを備えている。気室35側には給排気ノズル37が連通し、この給排気ノズル37を介して気室35に気体を給排できる。ちなみに、この給排気ノズル37には、IABP、補助人工心臓等で使用されている様な周知のエア駆動装置が接続され、心拍に同期させて気体の給排が行われる。一方、液室33には流出口39が連通し、この流出口39にカニューレ1が接続されている。

【0023】なお、コネクタ5には、図1に示した通り、チューブ15内に連通する側チューブ41が設けられ、側チューブ41の端部には三方活栓43が設けられている。この側チューブ41は、チューブ15内の圧力を監視したり、抗血栓剤や造影剤などの投与を行うのに

利用される。

【0024】次に、上記補助循環装置の使用方法について説明する。補助循環の実施に当たっては、カニューレ1を、例えば右鎖骨下動脈から挿入し、先端部材15aを左心室内にまで挿入すると共に、吐出口13は大動脈内に位置させる。ちなみに、チューブ15の挿入は、従来のカニューレと同様にスタイレットを用いて行われる。この際、先端部材15aは、最先端が略半球状とされているので、挿入抵抗が低減されると同時に、血管内面を傷つける可能性も少なくなる。また、吐出弁19は、チューブ15に密着しているの、挿入の妨げとなることがなく、特に、吐出弁19の両端がチューブ15に接着されているので、血管内に挿入、抜去する際に端部からめくれる様なことがなく、確実且つスムーズに挿入、抜去を行える。また、チューブ15には補強部材21を設けてあるので、血管内への挿入時にチューブ15に折れ曲がりが生じにくく、挿入操作をスムーズに実施することができる。

【0025】先端部材15aおよび吐出口13が上述の位置に至った後、スタイレットを抜去し、カニューレ1と血液ポンプ3とを接続する。また、側チューブ41からカニューレ1および血液ポンプ3内の空気抜きを行う。なお、血液ポンプ3は、事前にエア駆動装置（図示略）に接続されている。

【0026】続いて、エア駆動装置を稼働させて、例えば患者の心拍に同期させて血液ポンプ3への空気の給排を行い、気室35の圧力を増減変化させる。気室35を減圧させると、図2(a)に示す様に、液室33およびチューブ15内が陰圧状態となるので、血液が吸入口11からチューブ15を経て液室33へと流入する。この際、吸入弁17は、流入する血液により内側にすぼまるように変形するため、吸入口11からの血液の流入は阻害されない。しかも、4箇所の吸入口11の開口面積の総計は、チューブ15の径方向の断面積よりも大きいので、血液の流入は良好である。一方、吐出弁19は、チューブ15の内側と外側（即ち、大動脈側）との圧力差により、吐出口13に吸引されて吐出口13を被覆しているため、吐出口13からチューブ15内へ血液が流入することはない。このため、血液ポンプ3による血液の吸入は、左心室のみからとなる。

【0027】次に、気室35を増圧させると、図2(b)に示す様に、気室35に対して液室33の圧力が相対的に低くなるので、隔壁31は収縮変形し、液室33の容積が減少する。液室33の容積減少により、液室33内の血液はチューブ15側へ吐出される。吸入弁17は、チューブ15内の血液の圧力により先端部材15aに向かって押圧され、吸入口11に密着する。したがって、吸入口11からの血液の流出は阻止される。一方、チューブ15内の血液の圧力は、吐出弁19を内側から外側へと押圧するので、吐出弁19は、風船の様に

膨らみ、スリット19aを介して、血液が吐出口13から大動脈へ流出する。また、血液ポンプ3の吐出圧はチューブ15内の血液を介して大動脈側の血液に伝達され、大動脈内の血圧を昇圧する。

【0028】この様に、上記補助循環装置によれば、血液ポンプ3の圧力を増減することにより、左心室の血液を吸入口11から吸入し、吐出口13から大動脈に吐出する。これにより、左心室から大動脈側への血流を発生させ、流量補助ができる。また、大動脈内への血液の吐出に伴って大動脈内の血圧を昇圧できる。しかも、血液ポンプ3からの圧力に応じてチューブ15内の圧力が陰圧から陽圧、陽圧から陰圧へと交互に切り替わるので、拍動的な圧補助ができる。さらに、左心室の収縮時に左心室内の血液を吸入するので、収縮に際しての心臓の負担が低減される。したがって、本補助循環装置によれば、心臓の負担を増加させることなく、流量補助と拍動的な圧補助とが実現され、その上、心停止状態にあっても上述のように血流と拍動とを確保できるので、心停止時の補助循環としてきわめて有効である。

【0029】また特に、チューブ15に補強部材21を設けたので、従来よりもチューブ15の外径寸法の細径\*

\*化を図ることができ、しかも、チューブ15の柔軟性が高くなって挿入時等に折れ曲がりにくくなる。以上、本発明の実施形態について説明したが、本発明の具体的な構成については、上記以外にも、本発明の要旨を逸脱しない範囲内の種々なる態様を採用することができる。

【0030】例えば、上記例では、血液ポンプとしては、上述の空気圧駆動によるものの他に、往復ピストン式のポンプやダイヤフラムポンプ等を採用できる。

#### 【図面の簡単な説明】

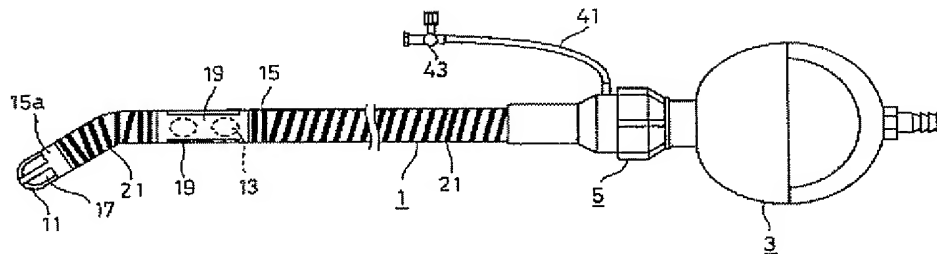
【図1】 補助循環装置を示す正面図である。

【図2】 補助循環装置の動作状態を示す模式図で、(a)は吸入状態、(b)は吐出状態を示す。

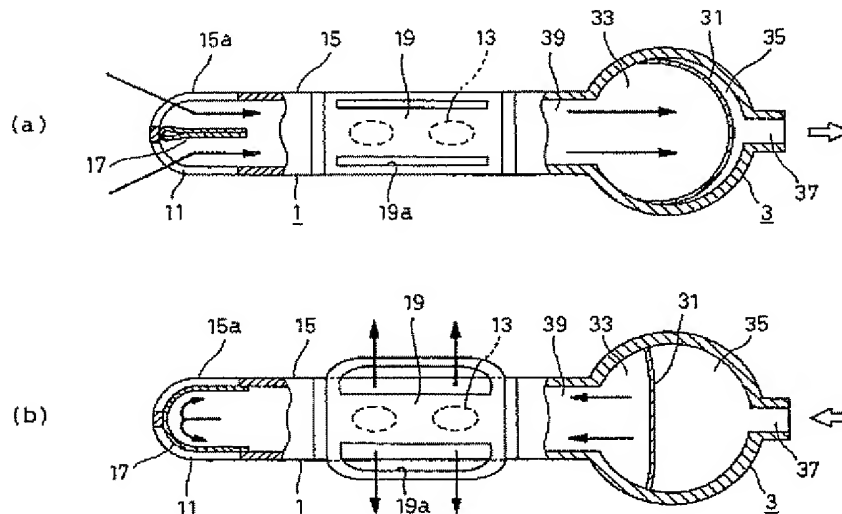
#### 【符号の説明】

1・・・カニューレ、3・・・血液ポンプ、5・・・コネクタ、11・・・吸入口、13・・・吐出口、15・・・チューブ、15a・・・先端部材、17・・・吸入弁、19・・・吐出弁、19a・・・スリット、21・・・補強部材、31・・・隔壁、33・・・液室、35・・・気室、37・・・給排気ノズル、39・・・流出口、41・・・側チューブ、43・・・三方活栓。

【図1】



【図2】



# PATENT ABSTRACTS OF JAPAN

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## (54) CANNULA AND SUPPLEMENTAL CIRCULATION DEVICE

### (57)Abstract:

**PROBLEM TO BE SOLVED:** To provide a cannula, which is possible to make the outer diameter smaller than before, further, which has higher flexibility and which is hard to be bent over, and a supplemental circulation device.

**SOLUTION:** A supplemental device is equipped with a cannula and a blood pump 3, and the cannula 1 is equipped with a flexible tube 15 having a suck-in opening 11 and a discharge-spout 13, a suck-in valve 17 which allows liquid to flow into the tube 15 from the suck-in opening 11 while the same prevents liquid to flow out from inside of the tube 15 to the outside of the suck-in opening 11, and a discharging valve 19, made of a flexible film, which allows liquid to flow out from the inside of the tube 15 to the outside of the discharge-spout 13, while the same prevents liquid to flow in the tube 15 from the discharge-spout 13. The inside of the material of the tube 15 is fixed with a reinforcement part 21. The reinforcement part 21 is a belt of stainless steel spirally coiled with one side of the belt facing the outer and the other side to the inner of the tube circumference.



**\* NOTICES \***

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1.This document has been translated by computer. So the translation may not reflect the original precisely.

2.\*\*\* shows the word which can not be translated.

3.In the drawings, any words are not translated.

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**CLAIMS**

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[Claim(s)]

[Claim 1]A flexible resin tube which has an admission port which carries out an opening to one end, and the delivery which maintained set distance from this admission port, and was drilled by side attachment wall.

A suction valve portion of the shape of a flexible film which prevents an outflow of a fluid to said admission port out of said resin tube while it is installed inside said resin tube to said admission port and an inflow of a fluid from said admission port to into said resin tube is permitted.

A discharge valve of the shape of a flexible film which prevents an inflow of a fluid from said delivery to into said resin tube while said delivery is covered, it is installed by the periphery side of said resin tube and an outflow of a fluid to said delivery out of said resin tube is permitted.

It is the cannula provided with the above, consisted of said resin tube and metal fabricated spirally [ of approximately the same diameter ], and had a reinforcing member which adhered to this resin tube in a form which winds said resin tube.

[Claim 2]Cannula with which said reinforcing member consists of a long picture band form in the cannula according to claim 1, and one field of this band form is characterized by being spirally fabricated in inner circumference and a form where a field of another side serves as a periphery.

[Claim 3]An assisted circulation apparatus comprising:

Cannula given in either claim 1 or claim 2.

A pump which carries out the regurgitation of the fluid for a fluid from said cannula to said cannula via inhalation or said outflow entrance via said outflow entrance by having a fluid chamber which is open for free passage to an outflow entrance which is open for free passage at the end of another side of said resin tube of this cannula, and these inflow outlets, and changing capacity of this fluid chamber.

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[Translation done.]



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3.In the drawings, any words are not translated.

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**DETAILED DESCRIPTION**

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[Detailed Description of the Invention]

[0001]

[Field of the Invention]It is inserted in the left ventricle thru/or a main artery, applying it, and it relates to the cannula used for auxiliary circulation of the blood flow by inhaling blood from the left-ventricle side and carrying out the regurgitation to the main artery side, and the assisted circulation apparatus equipped with this cannula.

[0002]

[Description of the Prior Art]As everyone knows, treatment by mechanical assistance circulation may be performed besides therapies, such as medication and oxygen inhalation, to the cardiac insufficiency of progressiveness and irreversibility, such as chronic heart failures, such as a valvular disease, and an cardiogenic shock after acute myocardial infarction and an open heart surgery.

[0003]As a kind of the device to carry out, this mechanical assistance circulation an applicant for this patent, In JP,7-231934,A, it was applied and inserted in the left ventricle thru/or a main artery, and the cannula which inhales blood from the left-ventricle side and carries out the regurgitation to the main artery side, and the assisted circulation apparatus equipped with this cannula are already proposed. According to this cannula and assisted circulation apparatus, without making the burden of the heart increase, flow assistance and pulsation \*\*\*\*\* could be realized and it was very effective also as auxiliary circulation at the time of cardiac arrest.

[0004]

[Problem(s) to be Solved by the Invention]However, according to the cannula and assisted circulation apparatus of the above-mentioned former, only the inside diameter which secures a required blood flow rate first is required, since only the intensity which is moreover equal to an internal boost and decompression at cannula is needed, for satisfying these conditions -- the outer diameter of a resin made pipe -- rather -- thick -- not forming -- it did not obtain, but when inserting cannula into a blood vessel, there was a problem that a patient's burden was heavy.

[0005]The resin tube which has intensity in this appearance suitably [ an outer diameter is thick and ], Since it is easy to become what lacks in pliability, if it should be easy to generate bending (kink) when it inserts in the curved blood vessel and should bend, There was also a problem that inserting operation will become difficult if it is at the insertion time, and expected auxiliary circulation was no longer made unless it will cope with it immediately, if it is [ auxiliary circulation ] under operation.

[0006]this invention is made in order to solve the above-mentioned problem, and it comes out. A twist can also attain narrow diameter-ization of an outside diameter size and the purpose has it in providing the cannula with which pliability is high and moreover cannot bend easily, and the assisted circulation apparatus equipped with the cannula.

[0007]

[The means for solving a technical problem and an effect of the invention] The flexible resin tube which has the delivery which, as for this invention, the passage according to claim 1 maintained set distance from the admission port which carries out an opening to one end, and this admission port, and was drilled by the side attachment wall in order to attain the above-mentioned purpose, The suction valve portion of the shape of a flexible film which prevents the outflow of the fluid to said admission port out of said resin tube while it is installed inside said resin tube to said admission port



and the inflow of the fluid from said admission port to into said resin tube is permitted, While said delivery is covered, it is installed by the periphery side of said resin tube and the outflow of the fluid to said delivery out of said resin tube is permitted, In the cannula provided with the discharge valve of the shape of a flexible film which prevents the inflow of the fluid from said delivery to into said resin tube, It consisted of said resin tube and metal fabricated spirally [ of approximately the same diameter ], and had the reinforcing member which adhered to this resin tube in the form which winds said resin tube.

[0008]In the above-mentioned composition, a resin tube and of approximately the same diameter, In a form which winds a resin tube by a reinforcing member by meaning having an outer diameter more than an inside diameter of a resin tube, and having an inside diameter below an outer diameter of a resin tube at least, and choosing such size. A reinforcing member can be adhered to a periphery of a resin tube, inner circumference, or meat.

[0009]It is used for it, locating an admission port in the left-ventricle side, and locating [ , for example from a right subclavian artery, cannula of this invention constituted as mentioned above makes the admission port side a head, and inserts a resin tube (only henceforth a tube) provided with a reinforcing member, and ] a delivery in the main artery side on both sides of an aortic valve. At this time, it leaves the other end (hand side edge) of a tube to the outside of the body, and it is connected to an outflow entrance of a pump which performs inhalation and regurgitation by turns from a single outflow entrance after that. In advance of use, air extraction in cannula and a pump is carried out.

[0010]Since inside of a tube will be in a negative pressure state relatively when a pump is in a suction stroke, a suction valve portion will be in an open state, and blood in left ventricle flows into a tube from an admission port. On the other hand, since inside of a tube will be in a positive pressure state relatively when a pump is in a discharging stroke, a discharge valve will be in an open state and blood in a tube flows into a main artery. In this case, a discharge pressure of a pump is transmitted to blood by the side of a main artery via blood in a tube, and \*\*\*\*s blood pressure in a main artery.

[0011]Thus, according to inhalation and regurgitation of a pump, a blood flow from left ventricle to a main artery is generated, and flow assistance can be performed. And since a pressure in a tube changes from negative pressure to positive pressure and negative pressure by turns from positive pressure corresponding to inhalation and a discharging stroke of a pump, pulsation \*\*\*\*\* is made. So that a blood pump may be inhaled, for example at the time of left-ventricle contraction and the regurgitation may be carried out at the time of left ventricular enlargement, If it is made to work to compensate for pulsation of the heart, since blood in left ventricle is inhaled at the time of left-ventricle contraction, a burden of the heart for contraction is reduced, and it will \*\*\*\* blood pressure in a main artery at the same time blood supplied to a main artery at the time of left ventricular enlargement increases. Since left ventricle and a main artery are intercepted by an aortic valve at the time of left ventricular enlargement, blood breathed out in a main artery from cannula does not flow into the left-ventricle side.

[0012]Therefore, flow assistance and pulsation \*\*\*\*\* are realized, without making a burden of the heart increase. Since a blood flow and pulsation are securable as mentioned above even if it is in a cardiac arrest state, it is very effective as auxiliary circulation at the time of cardiac arrest. Since especially cannula of this invention has provided a reinforcing member like \*\*\*\* in a resin tube, even if it makes thickness of a tube thin, it has only the intensity which is equal to an internal boost and decompression. Therefore, even when an inside diameter equivalent to elegance is set up conventionally, an outer diameter can be made thinner than the conventional resin tube, it is hard to cause an interruption in the circulation etc., and a burden of a patient at the time of insertion into a blood vessel is eased. Since a reinforcing member has adhered in a form wound spirally, pliability which a resin tube originally has is not lost, Since only a part whose intensity of a tube improved can make thickness of resin itself thin and can moreover also use a softer resin material than before rather, conventionally, pliability can be made high, and also when it inserts in a curved blood vessel, bending does not generate it.

[0013]By the way, if metal wire material is fabricated spirally, the above-mentioned reinforcing member, For example, although not limited in particular for sectional shape of the metal wire material itself, said reinforcing member consists of like and a long picture band form, and if one field of this band form is spirally fabricated in inner circumference according to claim 2 and a form where a field

of another side serves as a periphery, It is advantageous at a point that narrow diameter-ization can be attained more, securing required intensity.

[0014]Namely, although a band form here becomes [ a certain amount of width and its width ] and has thin thickness, Since required intensity is securable by enlarging a width dimension even if a width dimension of a band form becomes somewhat thin if one field of a band form fabricates such a band form in inner circumference and a form where a field of another side serves as a periphery, spirally, Compared with a case where a wire rod of round bar shape and the shape of a square bar is spirally fabricated so that it may become comparable intensity, thickness of the reinforcing member itself can be made thin. Therefore, it is very suitable to attain narrow diameter-ization of cannula.

[0015]The assisted circulation apparatus according to claim 3 The cannula according to claim 1 or 2, By having a fluid chamber which is open for free passage to an outflow entrance which is open for free passage at the end of another side of said resin tube of this cannula, and these inflow outlets, and changing capacity of this fluid chamber, Since it had a pump which carries out the regurgitation of the fluid for a fluid from said cannula to said cannula via inhalation or said outflow entrance via said outflow entrance, auxiliary circulation using the above-mentioned cannula can be carried out, and an effect as the above-mentioned cannula was described is demonstrated.

[0016]

[Embodiment of the Invention]Next, the embodiment of this invention is described based on a drawing. The cannula and assisted circulation apparatus which are explained below are only an example of the embodiment of this invention, and the constituent means of this invention is not limited to a following concrete device etc.

[0017]As an assisted circulation apparatus is shown in drawing 1, it has the cannula 1 and the blood pump 3, and both are connected by the connector 5. The above-mentioned cannula 1 is provided with the following.

The flexible tube 15 which has the admission port 11 and the delivery 13.

The suction valve portion 17 of the shape of a flexible film which prevents the outflow of the fluid to the outside out of the tube 15 of the admission port 11 while it is installed inside the tube 15 to the admission port 11 and the inflow of the fluid from the admission port 11 to into the tube 15 is permitted.

The discharge valve 19 of the shape of a flexible film which prevents the inflow of the fluid from the delivery 13 to into the tube 15 while the delivery 13 is covered, it is installed by the periphery side of the tube 15 and the outflow of the fluid to the outside out of the tube 15 of the delivery 13 is permitted.

[0018]The admission port 11 is drilled among this by the four end members 15a with which the tip of the tube 15 was equipped, and that inside is equipped with the suction valve portion 17 made from segmented polyurethane. As shown in the mimetic diagram of drawing 2 (b), this suction valve portion 17 is the shape stuck to the inner circumference side of the admission port 11, and only that center has pasted it up inside the end member 15a. Therefore, when the inside of the tube 15 becomes negative pressure, As shown in drawing 2 (a), while changing into the shape which does not oppose the fluid which flows from the outside, when the inside of the tube 15 becomes positive pressure, as shown in drawing 2 (b), it returns to the shape stuck to the inner circumference side of the admission port 11, and the outflow of the fluid to the exterior is prevented.

[0019]On the other hand, three-place (namely, a total of six pieces) formation of the delivery 13 is carried out 120 degrees as 2 sets [ 1 ] in a rotation symmetric position, and it is equipped with the discharge valve 19 made from segmented polyurethane so that the periphery may be covered. The discharge valve 19 is tubed [ which is stuck to the periphery of the tube 15 ], and both ends have pasted it up on the peripheral face of the tube 15. A total of three slits 19a are formed in the 120-degree rotation symmetric position which becomes alternate [ the delivery 13 ] at this discharge valve 19. By this, when the inside of the tube 15 becomes negative pressure, While the discharge valve 19 covers and sticks the delivery 13, when the inside of the tube 15 becomes positive pressure, the fluid which expanded as the discharge valve 19 showed drawing 2 (b), flowed out of the delivery 13, and flowed between the delivery 13 and the discharge valve 19 flows out outside via the slit 19a.

[0020]As characteristic composition in the above-mentioned cannula 1, into the meat of the tube 15, the reinforcing member 21 has adhered as shown in drawing 1. This reinforcing member 21 is what

wound band-like stainless lines spirally, turns one field of a belt to a periphery, and it is drawing the spiral in the form where the field of another side used as that back side is turned to inner circumference. Rather than the delivery 13, the reinforcing member 21 adheres to two fields from the proximal edge side to near the proximal edge of the tube 15 rather than the delivery 13 the distal end side from near the tip of the tube 15, and is not allocated near [ delivery 13 ] in the meantime.

[0021]The outside diameter size of the tube 15 can be made thin, securing intensity and an inner diameter dimension equivalent to the former, since the intensity of the tube 15 will improve if such a reinforcing member 21 is formed. What had more specifically become an outer diameter of about about 7.5–8.5 mm conventionally which has not formed the reinforcing member 21 in the case of elegance when an inside diameter of 5.5 mm was secured is forming the reinforcing member 21. Even if it secures same inside diameter of 5.5 mm, it comes to be able to carry out [ narrow diameter ]-izing of the outer diameter to about about 6.5–7.5 mm. Therefore, it is expected that application to a patient with a thinner vessel diameter and the case which becomes possible and causes an interruption in the circulation etc. decrease more.

[0022]Now, on the other hand, the blood pump 3 is provided with the fluid chamber 33 and the air space 35 which were divided by the septum 31 of the shape of a flexible film which can change into an inside freely, as shown in drawing 2 (a) and the figure (b). To the air space 35 side, the air-supply-and-exhaust nozzle 37 is open for free passage, and the feeding and discarding of the gas can be carried out to the air space 35 via this air-supply-and-exhaust nozzle 37. Incidentally the exhaust air drive of common knowledge which is used by IABP, an assisted artificial heart, etc. is connected to this air-supply-and-exhaust nozzle 37, it is made to synchronize with a heartbeat, and gaseous feeding and discarding are performed. On the other hand, it flows into the fluid chamber 33, the entrance 39 is open for free passage, and the cannula 1 is connected to this outflow entrance 39.

[0023]The side tube 41 which is open for free passage in the tube 15 as shown in drawing 1 is formed in the connector 5, and the three-way cock 43 is formed in the end of the side tube 41. The side [ this ] tube 41 is used for supervising the pressure in the tube 15 or prescribing a vantithrombotic, a contrast medium, etc. for the patient.

[0024]Next, the directions for the above-mentioned assisted circulation apparatus are explained. In implementation of auxiliary circulation, insert the cannula 1, for example from a right subclavian artery, and the end member 15a is inserted even into the left ventricle, and the delivery 13 is located in a main artery. Incidentally, insertion of the tube 15 is performed using the stylette like the conventional cannula. under the present circumstances, the end member 15a — a tip — abbreviated — a possibility of damaging a blood vessel inner surface also decreases at the same time insertion resistance is reduced, since it is hemispherical. Since it did not become the hindrance of having stuck to the tube 15, and insertion and the both ends of the discharge valve 19 have pasted the tube 15 especially, in a blood vessel, the discharge valve 19 is not turned over from an end, when carrying out extraction, insertion and, and can perform insertion and extraction certainly and smoothly. Since the reinforcing member 21 is formed in the tube 15, it is hard to produce bending in the tube 15 at the time of insertion into a blood vessel, and inserting operation can be carried out smoothly.

[0025]After resulting in the position with the end member 15a and the above-mentioned delivery 13, extraction of the stylette is carried out and the cannula 1 and the blood pump 3 are connected. The air extraction in the cannula 1 and the blood pump 3 is performed from the side tube 41. The blood pump 3 is connected to the exhaust air drive (graphic display abbreviation) a priori.

[0026]Then, work an exhaust air drive, for example, it is made to synchronize with a patient's heartbeat, the feeding and discarding of the air to the blood pump 3 are performed, and the increasing and decreasing change of the pressure of the air space 35 is carried out. Since the inside of the fluid chamber 33 and the tube 15 will be in a negative pressure state as shown in drawing 2 (a) if the air space 35 is made to decompress, blood flows into the fluid chamber 33 through the tube 15 from the admission port 11. Under the present circumstances, since the suction valve portion 17 changes so that it may narrow inside with the flowing blood, the inflow of the blood from the admission port 11 is not checked. And since the total of the effective area product of the four admission ports 11 is larger than the cross-section area of the diameter direction of the tube 15, the inflow of blood is good. On the other hand, since the discharge valve 19 was attracted in the delivery 13 and has covered the delivery 13 with the pressure differential of the inside of the tube 15, and the outside (namely, the main artery side), blood does not flow into the tube 15 from the delivery 13. For this reason,

inhalation of the blood by the blood pump 3 consists only of left ventricle.

[0027]Next, since the pressure of the fluid chamber 33 will become low relatively to the air space 35 as shown in drawing 2 (b) if the air space 35 is made to \*\*\*\*, shrinkage deforming of the septum 31 is carried out, and the capacity of the fluid chamber 33 decreases. The blood in the fluid chamber 33 is breathed out by capacity reduction of the fluid chamber 33 to the tube 15 side. The suction valve portion 17 is pressed by the pressure of the blood in the tube 15 toward the end member 15a, and is stuck to the admission port 11. Therefore, the outflow of the blood from the admission port 11 is prevented. On the other hand, since the pressure of the blood in the tube 15 presses the discharge valve 19 outside from the inside, the discharge valve 19 swells like a balloon and blood flows out of the delivery 13 into a main artery via the slit 19a. The discharge pressure of the blood pump 3 is transmitted to the blood by the side of a main artery via the blood in the tube 15, and carries out pressure up of the blood pressure in a main artery.

[0028]Thus, according to the above-mentioned assisted circulation apparatus, by fluctuating the pressure of the blood pump 3, the blood of the left ventricle is inhaled from the admission port 11, and the regurgitation is carried out to a main artery from the delivery 13. Thereby, the blood flow from the left ventricle to the main artery side is generated, and flow assistance can be performed. In connection with the regurgitation of the blood into a main artery, the pressure up of the blood pressure in a main artery can be carried out. And since the pressure in the tube 15 changes from negative pressure to positive pressure and negative pressure by turns from positive pressure according to the pressure from the blood pump 3, pulsation \*\*\*\*\* is made. Since the blood in the left ventricle is inhaled at the time of contraction of the left ventricle, the burden of the heart for contraction is reduced. Therefore, since according to this assisted circulation apparatus a blood flow and pulsation can be secured as mentioned above, without making the burden of the heart increase even if flow assistance and pulsation \*\*\*\*\* are realized and it is moreover in a cardiac arrest state, it is very effective as auxiliary circulation at the time of cardiac arrest.

[0029]Since the reinforcing member 21 was especially formed in the tube 15, narrow diameter-ization of the outside diameter size of the tube 15 can be attained conventionally, and moreover, the pliability of the tube 15 becomes high and becomes difficult to bend at the time of insertion, etc. As mentioned above, although the embodiment of this invention was described, about the concrete composition of this invention, the mode within the limits which do not deviate from the gist of this invention besides the above which becomes various is employable.

[0030]For example, in the above-mentioned example, a pump, a diaphragm pump, etc. of a both-way piston type other than what is depended on an above-mentioned pneumatic system are employable as a blood pump.

[Translation done.]

## \* NOTICES \*

JPO and INPIT are not responsible for any damages caused by the use of this translation.

1.This document has been translated by computer. So the translation may not reflect the original precisely.

2.\*\*\* shows the word which can not be translated.

3.In the drawings, any words are not translated.

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## DESCRIPTION OF DRAWINGS

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[Brief Description of the Drawings]

[Drawing 1]It is a front view showing an assisted circulation apparatus.

[Drawing 2]By the mimetic diagram showing the operating state of an assisted circulation apparatus, as for an inhalation state and (b), (a) shows a discharging state.

[Description of Notations]

1 [ ... Admission port, ] ... Cannula, 3 ... A blood pump, 5 ... A connector, 11 13 [ ... Suction valve portion, ] ... A delivery, 15 ... A tube, 15a ... An end member, 17 19 [ ... A septum, 33 / ... A fluid chamber, 35 / ... Air space, 37 / ... An air-supply-and-exhaust nozzle, 39 / ... An outflow entrance, 41 / ... A side tube, 43 / ... Three-way cock. ] ... A discharge valve, 19a ... A slit, 21 ... A reinforcing member, 31

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[Translation done.]

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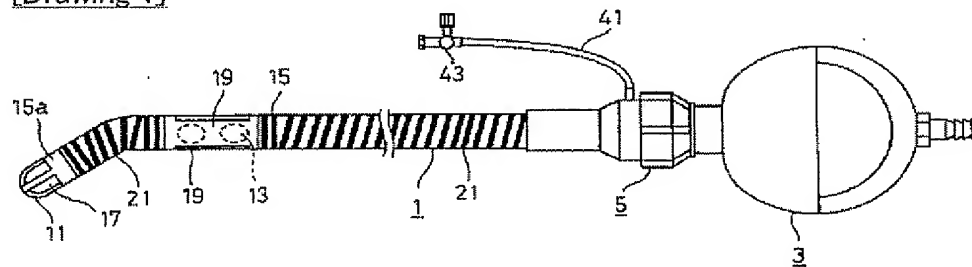
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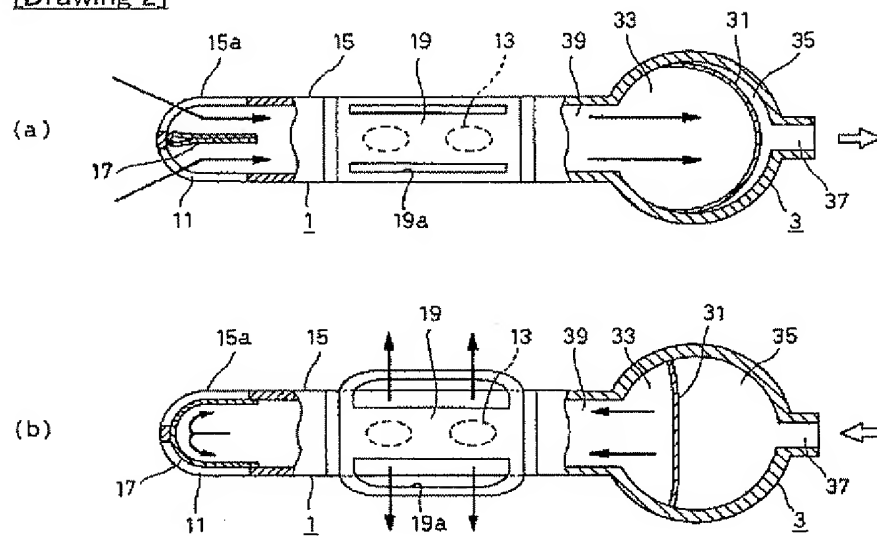
3.In the drawings, any words are not translated.

DRAWINGS

[Drawing 1]



[Drawing 2]



[Translation done.]